# Kansas Immunization Program
# Vaccine Management

The Vaccines for Children (VFC) Program requires the Kansas Immunization Program ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business and medical practices and do not result in unnecessary costs to the program due to excessive wastage or unaccounted for VFC vaccines. The CDC has established a storage and handling toolkit that details the steps of good vaccine management. This toolkit is found at: http://www.2a.cdc.gov/nip/isd/shtoolkit/splash.html

Kansas VFC providers have been very responsive in modifying their practices to ensure sound vaccine management practices are conducted. The Kansas Immunization Program appreciates your efforts in these endeavors. There is still work to be done so this policy is aimed at facilitating quality improvements in VFC vaccine management practices to reduce the wasted vaccines from 3.5% to less than 1% and to reduce unaccounted for vaccines from 5.8% to less than 2% by 2012. Losses due to wasted and unaccounted for VFC vaccines exceeded a million dollars in Kansas which can lead to fewer eligible children receiving their needed immunizations.

The following constitute procedural direction for the management of VFC and state-supplied vaccines:

**Storage and Handling**

**Appropriate vaccine storage ensures vaccines are viable to protect against disease by ensuring the potency of the vaccine which allows the recipient to develop an immune response and promotes herd immunity.**

1. Vaccines should be handled and stored in accordance with the Food and Drug Administration (FDA) –approved package insert that is shipped with each product. Additional guidance for storage and handling of vaccines is contained in the CDC Vaccine Storage & Handling Toolkit as referenced above.
2. A "Do Not Unplug" warning sign should be placed next to the electrical outlets for each vaccine storage refrigerator and freezer and on the electrical breaker that services these outlets. Tamper proof plugs are also suggested
3. A calibrated certified thermometer should be used in each vaccine storage unit. The calibration and certification need to be updated or unit replace periodically so it is recommend the units in use be checked at least annually to assure they are still within their calibration/certification dates. KIP supplied digital thermometers meet this requirement.
4. The temperature of the refrigerator and freezer where the vaccines are stored should be checked and recorded on a temperature log at least twice daily. Preferably when the clinic opens and just before closing. Clinic absences of greater than 3 days will require someone check and record temperatures beginning with the fourth day the clinic is closed.

5. If there is a refrigerator or freezer power outage or malfunction, the time interval of the outage needs to be determined as this is critical to determine the viability of the vaccines.
6. VFC providers need to develop contingency plans to assure vaccine viability in the case or natural disasters, power outages, or other non-planned for emergencies. Such contingency plans might be a back-up generator or moving vaccines to another location

which have a generator. A template for emergency procedures is found in the Immunization Manual.

7. Any incident which may call into question the vaccine viability, including incidents of improper vaccine storage and handling, must be reported to KIP and the vaccine manufacturers. The report needs to include vaccine antigens and length of time and temperature at which vaccine was stored. Not all vaccines are non-viable if the temperature excursion and time factors were minimal. Mark vaccines DO NOT USE and leave refrigerated or frozen until the manufacturer and KIP have been notified. Frozen vaccines are more sensitive to warm temperature just as refrigerated vaccine is most sensitive to cold temperature.
8. Once the vaccines are determined to be non-viable, place them in a container and mark DO NOT USE. Complete the KIP Wasted Vaccine Form; document the wasted doses on the Monthly Immunization Report or KSWebIZ reconciliation. Fax the wasted form to KIP at 785-296-6510 each month with the Monthly Immunization Report.
9. Pack the wasted vaccines in a shipping box and contact KIP so we may request a return shipping label from McKesson.

**Vaccine Ordering**

**Vaccine ordering is more than placing the orders. It is analysis of the numbers of children served over what time frame, determining the vaccine manufacturer and presentation the clinic will use, assessing storage capacity and having written vaccine storage and handling policies that are communicated and followed by staff.**

1. Ordering the appropriate amount of each vaccine at the correct interval is an important component of vaccine accountability.
2. Providers need to calculate their vaccine needs based on the numbers of children served in each age cohort. A template to assist the provider in this calculation is found in the exhibits.
3. In 2010 the CDC placed all VFC providers in "*Economic Ordering Tiers*." These four tiers are based on annual vaccine doses *administered*. KIP began working with providers to implement this mid-2010. Currently the four tiers and ordering frequency are:
    a. 6,000 annual doses: Order monthly
    b. 800-5,999 doses: Order bi-monthly
    c. 200-799 doses: Order quarterly
    d. Less than 199 doses: Order as needed
4. Vaccine management includes deciding which vaccine manufacturer and presentation to use. This helps improve staff knowledge of the vaccines administered, decreases errors in vaccine administration and streamlines the inventory. These factors decrease wastage and unaccounted for vaccines.
5. It is recommended providers count vaccines at least monthly, or more often when large vaccine stores are kept on hand. This will assist in identifying discrepancies in vaccine counts or administration early.
6. Designate one-person and at least one back-up as responsible for ensuring vaccine shipments are received, stored and handled properly.
7. A Routine Vaccine Storage and Handling Plan Worksheet template is found in the Immunization Manual. This template will assist in documenting and training staff on the importance of vaccine management.
8. Open shipments immediately and store appropriately.
9. Enter new inventory information immediately.
10. Separate new vaccine shipments from those currently in stock. Use those in stock first to assure vaccine with the earliest expiration date is used first.
11. If a provider receives vaccines they did not order: Contact KIP and McKesson at once.

12. Over ordering vaccines which result in waste is avoidable.
13. Providers may place the excess doses on the KIP Re- distribution list if:
    a) the vaccine has a minimum or 90 days and a maximum of 365 days before the vaccine's expiration date;
    b) the ordering provider is responsible for any doses which expire on the redistribution list that have not been accepted for transfer to another VFC provider;
    c. providers accepting vaccine from the redistribution list are responsible for using the doses once they are transferred. KIP encourages providers to accept only doses they can administer before the expiration date;
    d. the transferring and receiving provider will document these doses on their monthly MIR/reconciliation reports as transferred vaccines.

**Vaccine Storage Units**

**The CDC's storage and handling toolkit (referenced above) describes in detail minimum acceptable vaccine storage units. KIP recommends these guidelines be followed as the minimum vaccine storage:**

1. Vaccines may **not** be stored in "dorm style" refrigerators. These units do not allow for consistent temperature control and are prohibited by the CDC.
2. Refrigerator-only and stand-alone freezers for providers who store between 1,000 and 4,999 doses annually.
3. Commercial-grade or biologic-grade refrigerator-only units when 5,000 or greater doses are administered annually.
4. Household combination refrigerator/freezer units with dual temperature controls are acceptable if less than 1,000 doses administered annually so long as they meet minimum requirements as outlined in the CDC toolkit.
5. Vaccine many never be stored in doors, storage trays, or next to the defrosting units on self-defrosting models.
6. Alarms and/or back up generators are strongly encouraged to help prevent vaccine wastage due to storage and handling.

**Specific documents referenced above are found in the Immunization Program Manual at: www.kdheks.gov/immunize**

1. Vaccine Storage and Emergency Response Plan
2. Wasted Vaccine Return Procedure
3. Routine Vaccine Storage & Handling Plan
4. Wasted Vaccine Policy
5. Unaccounted for Vaccine Policy
6. VFC Vaccine Borrowing Policy